

REMARKS

This paper is responsive to the Office Action dated August 5, 2002 (Paper No. 11), which is the first action on the merits of the application.

Claims 21-58 were previously pending in the application and under examination. Upon entry of this Amendment, claim 21 is reworded and claim 59 is added. The amendments to claim 21 are supported in Section VIII, beginning on page 118. Claim 59 is supported *inter alia* on page 117 line 29 to page 118 line 1. Accordingly, the amendments do not add new matter to the disclosure.

Applicant acknowledges with gratitude that the Examiner has considered and made of record all of the information provided in the Information Disclosure Statements filed in this application.

Further consideration and allowance of the application is respectfully requested.

Interview

The undersigned wishes to express his gratitude to Examiner Malgorzata Walicka and Examiner Rebecca Prouty for kindly discussing this application with him at the U.S. Patent & Trademark Office on September 11, 2002.

Claims 21 and 59 are presented in this amendment in the form they were discussed at the interview. These and the other dependent claims are believed to be in condition for allowance.

Rejections under 35 USC § 112 ¶ 2:

Claim 21 stands rejected under this Section for referring to the telomerase as increasing the "proliferative capacity of the cell".

This term is defined in the specification on page 118, line 24 to page 119, line 9, as meaning that there is an increase in the number of divisions the cell can undergo before senescence. By way of this amendment, this definition is now placed into the claim explicitly.

Claim 21 also stands rejected for referring in part d) to measuring a "therapeutic effect" or "toxic effect" on the telomerized cells.

By way of this amendment, the language objected to has been removed from the claim. As explained during the interview, the benefit of this invention is the availability of cells having increased proliferative capacity. This provides cells that can be grown as needed to generate a large and consistent supply of cultured cells for any desirable purpose. The cells may be used for a number of

therapeutic and research objectives, as explained in the specification in Section VIII beginning on page 118, including but not limited to the screening or validation of various drugs. The outcome to be determined will be defined by the user, depending on the nature of the cell and the investigation being conducted, and in conformity with drug screening practices used in the art.

Newly added claim 59 refers to one possible outcome, which is determining whether the drug or drug candidate is lethal to the cell.

Claims 24 and 25 stand rejected for reciting a recombinant polynucleotide for which there is no antecedent basis. This has been amended to recite a nucleic acid, which has antecedent basis in Claim 21.

Withdrawal of these rejections is respectfully requested.

Drawings:

Applicant acknowledges the defects identified in the drawings, as indicated in the Notice of Draftsperson's Patent Drawing Review.

Applicant undertakes to provide replacement drawings that comply with the requirements upon indication that this application is otherwise in condition for allowance.

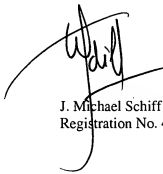
Conclusion

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and an early Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, applicant hereby requests an interview by telephone.

Should the Patent Office determine that an extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Assistant Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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Version with Markings to show

CHANGES MADE

USSN 09/721,456

Docket 018/211c

Amended Title:

HUMAN TELOMERASE CATALYTIC SUBUNIT

CELLS IMMORTALIZED WITH TELOMERASE REVERSE TRANSCRIPTASE
FOR USE IN DRUG SCREENING

Amendments to Claims:

21. A method of drug screening or validation of a drug_ comprising:
- a) obtaining a drug or drug candidate;
 - b) obtaining a cultured mammalian cell comprising a nucleic acid sequence that encodes a telomerase reverse transcriptase protein, variant, or fragment having telomerase catalytic activity when complexed with a telomerase RNA, wherein the nucleic acid sequence hybridizes under stringent conditions to a polynucleotide having a sequence complementary to SEQ. ID NO:1, and wherein the expression of the protein, variant, or fragment in the cell increases the ~~proliferative capacity of the cell~~ number of divisions the cell can undergo before senescence;
 - c) administering the drug or drug candidate to the cultured cell; and
 - d) determining ~~whether the drug or drug candidate has a therapeutic or toxic effect on the cell~~ if the drug or drug candidate has an effect on the cell.
22. The method of claim 21, wherein the cell is a human cell.
23. The method cell of claim 22, wherein the cell further comprises a selectable marker gene.
24. The method of claim 22, wherein the ~~recombinant polynucleotide~~ nucleic acid comprises a constitutive promoter.

25. The method of claim 22, wherein the ~~recombinant polynucleotide~~ nucleic acid comprises an inducible promoter.
26. The method of claim 22, wherein the cell is a liver cell.
27. The method of claim 26, wherein the cell is a hepatocyte.
28. The method of claim 22, wherein the cell is a nerve cell.
29. The method of claim 28, wherein the cell is a glial cell, astrocyte, or oligodendrocyte.
30. The method of claim 28, wherein the cell is a neuron of the central nervous system.
31. The method of claim 30, wherein the cell is a cholinergic or adrenergic cell.
32. The method of claim 22, wherein the cell is a retinal pigmented epithelial cell.
33. The method of claim 22, wherein the cell is a contractile cell.
34. The method of claim 33, wherein the cell is a heart muscle cell or smooth muscle cell.
35. The method of claim 22, wherein the cell is a fat cell.
36. The method of claim 22, wherein the cell is a fibroblast
37. The method of claim 22, wherein the cell is a vascular endothelial cell.
38. The method of claim 22, wherein the cell is a hormone secreting cell.
39. The method of claim 38, wherein the cell secretes insulin or glucagon.
40. The method of claim 38, wherein the cell is a pituitary cell, thyroid hormone secreting cell, or adrenal cell.
41. The method of claim 22, wherein the cell is a fat storing cell.
42. The method of claim 22, wherein the cell is an epithelial or mucosal cell.

43. The method of claim 42, wherein the cell is an oral cavity cell, stomach cell, or intestinal cell.
44. The method of claim 42, wherein the cell is a mammary gland, uterus, or prostate cell.
45. The method of claim 42, wherein the cell is an air space epithelial cell of the lung.
46. The method of claim 22, wherein the cell is a tubular cell of the kidney.
47. The method of claim 22, wherein the cell is a blood cell or a cell of the immune system.
48. The method of claim 47, wherein the cell is a T or B lymphocyte.
49. The method of claim 47, wherein the cell is a mast cell or eosinophil.
50. The method of claim 47, wherein the cell is a monocyte or macrophage.
51. The method of claim 22, wherein the cell is an osteoblast, osteocyte, or osteoclast.
52. The method of claim 22, wherein the cell is a chondrocyte or sinovial cell.
53. The method of claim 22, wherein the cell is a stem cell.
54. The method of claim 53, wherein the cell is an embryonic stem cell.
55. The method of claim 53, wherein the cell is an embryonic germ cell.
56. The method of claim 53, wherein the cell is an adult stem cell.
57. The method of claim 22, wherein the polynucleotide encodes a full-length, naturally occurring human telomerase reverse transcriptase.
58. The method of claim 22, wherein the polynucleotide encodes a human telomerase reverse transcriptase having the amino acid sequence of SEQ ID NO:2.
59. The method of claim 21, comprising determining whether the drug or drug candidate is lethal to the cell.

Upon allowance of the application, please renumber the claims as follows:

Claim 21 → 1
22 → 8
23 → 6
24 → 4
25 → 5
26 → 9
27 → 10
28 → 11
29 → 12
30 → 13
31 → 14
32 → 15
33 → 16
34 → 17
35 → 18
36 → 19
37 → 20
38 → 21
39 → 22
40 → 23

Claim 41 → 24
42 → 25
43 → 26
44 → 27
45 → 28
46 → 29
47 → 30
48 → 31
49 → 32
50 → 33
51 → 34
52 → 35
53 → 36
54 → 37
55 → 38
56 → 39
57 → 2
58 → 3
59 → 7